

Serial No. 10/743,116

Dkt.: P-11209.07

Filing Date: December 22, 2003

Title: ACTIVE AIR REMOVAL SYSTEM OPERATING MODES OF AN EXTRACORPOREAL BLOOD CIRCUIT

Claims

1 – 24 (Canceled).

25. (Amended) [[ The operating method of claim 22,]] A method of operating an active air removal (AAR) system to purge air from an integrated extracorporeal blood circuit providing extracorporeal oxygenation of a patient's blood during cardiopulmonary bypass surgery adapted to be performed in the presence of a perfusionist on a patient in an operating room, the operating method comprising:

providing an air removal device incorporated in the extracorporeal blood circuit,  
the air removal device comprising:

an air removal device housing enclosing a chamber;

an air removal device purge port through the housing to the chamber;

an air sensor supported by the air removal device housing adapted to provide an air sensor signal indicative of air in the air removal device housing;

an air removal device purge line coupled to the air removal device purge port and extending to a purge line connector adapted to be coupled to a vacuum source to apply suction to the air removal device purge port to draw air therefrom;

providing an AAR controller operating under the control of an AAR operating algorithm;

locating a portion of the air removal purge line extending through a purge valve of the AAR controller, the purge valve movable between a purge valve open position and a purge valve closed position;

coupling the air sensor with the AAR controller;

commencing the AAR controller operating algorithm that:

enters a self-test mode that performs specified self-tests of components and operating conditions of the AAR controller;

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progresses to a standby mode when self-tests are completed to monitor specified components and operating conditions of the AAR controller, to power the air sensor, and to monitor the air sensor signal; and responds to a perfusionist initiated command to enter an automatic mode from the standby mode enabling automatic movement of the purge valve from the closed position to the open position when the air sensor signal is indicative of air in the air removal device housing to allow air sensed in the air removal device to be purged through the purge line by the suction of the vacuum source;

wherein the AAR controller operating system is powered by a power supply adapted to be coupled to mains power or by a backup battery, and wherein a power state self-test is performed in the self-test mode comprising:

determining if the power supply is operative and capable of supplying operating power to the AAR controller operating system;

determining if the backup battery is present and capable of supplying operating power to the AAR controller operating system;

supplying operating power from the backup battery to the AAR controller operating system when the power supply is determined to be inoperative or incapable of supplying operating power to the AAR controller operating system and the backup battery is determined to be present and capable of supplying operating power to the AAR controller operating system; and

further comprising inhibiting the automatic movement of the purge valve from the closed position to the open position in the automatic mode when the air sensor signal is indicative of air in the air removal device housing if the power supply is determined to be inoperative or incapable of supplying operating power to the AAR controller operating system.

26. (Amended) The operating method of claim [[23]] 25, wherein the AAR controller further comprises a mechanical release button interconnected with the purge valve

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adapted to enable manual opening of the purge valve by the perfusionist in the standby and the automatic modes.

27. (Amended) The operating method of claim ~~[[21]]~~ 25, further comprising:  
determining an error state of the purging system; and  
alerting the perfusionist of the error state.

28. (Original) The purging method of claim 27, wherein the alerting step comprises:  
formulating alert message signals related to the determined error state; and  
displaying alert messages readable by the perfusionist on a display screen.

29. (Original) The purging method of claim 27, wherein the alerting step comprises:  
formulating alert sound signals related to the determined error state; and  
applying the formulated alert sound signals to a sound emitter that emits audible alert sounds that can be heard by the perfusionist.

30. (Original) The purging method of claim 27, wherein the alerting step comprises:  
formulating alert light signals related to the determined error state; and  
applying the formulated alert light signals to at least one light emitter that emits visual light in response to the alert light signals that can be seen by the perfusionist.

31. (Canceled) Please cancel claim 31.

32. (Canceled) Please cancel claim 32.

33. (Canceled) Please cancel claim 33.

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34. (Amended) [[ The operating method of claim 33,]] A method of operating an active air removal (AAR) system to purge air from an integrated extracorporeal blood circuit providing extracorporeal oxygenation of a patient's blood during cardiopulmonary bypass surgery adapted to be performed in the presence of a perfusionist on a patient in an operating room, the operating method comprising:

providing an air removal device incorporated in the extracorporeal blood circuit, the air removal device comprising:

an air removal device housing enclosing a chamber;

an air removal device purge port through the housing to the chamber;

an air sensor supported by the air removal device housing adapted to provide an air sensor signal indicative of air in the air removal device housing;

an air removal device purge line coupled to the air removal device purge port and extending to a purge line connector adapted to be coupled to a vacuum source to apply suction to the air removal device purge port to draw air therefrom;

providing an AAR controller operating under the control of an AAR operating algorithm;

locating a portion of the air removal purge line extending through a purge valve of the AAR controller, the purge valve movable between a purge valve open position and a purge valve closed position;

coupling the air sensor with the AAR controller;

commencing the AAR controller operating algorithm that:

enters a self-test mode that performs specified self-tests of components and operating conditions of the AAR controller;

progresses to a standby mode when self-tests are completed to monitor specified components and operating conditions of the AAR controller, to power the air sensor, and to monitor the air sensor signal; and responds to a perfusionist initiated command to enter an automatic mode from the standby mode enabling automatic movement of the purge valve from the closed position to the open position when the air sensor signal is

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indicative of air in the air removal device housing to allow air sensed in the air removal device to be purged through the purge line by the suction of the vacuum source;

determining an error state of the purging system; and inhibiting the automatic movement of the purge valve from the closed position to the open position in the automatic mode when an error state is detected;

wherein the error determining step comprises determining the presence of fluid in the purge line;

wherein the AAR controller further comprises a fluid in line (FIL) sensor arranged with respect to the purge valve, and further comprising: locating a further portion of the purge line through the FIL sensor; and powering the FIL sensor to develop a FIL sensor signal indicative of the absence or presence of fluid in the purge line, and wherein: the error determining step comprises determining the presence of fluid in the purge line from the FIL sensor signal; and

wherein the AAR controller further comprises a mechanical release button interconnected with the purge valve adapted to enable manual opening of the purge valve by the perfusionist.

35. (Canceled) Please cancel claim 35 without prejudice.

36. (Amended) [[ The operating method of claim 35,]] A method of operating an active air removal (AAR) system to purge air from an integrated extracorporeal blood circuit providing extracorporeal oxygenation of a patient's blood during cardiopulmonary bypass surgery adapted to be performed in the presence of a perfusionist on a patient in an operating room, the operating method comprising:

providing an air removal device incorporated in the extracorporeal blood circuit, the air removal device comprising:

an air removal device housing enclosing a chamber;

an air removal device purge port through the housing to the chamber;

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an air sensor supported by the air removal device housing adapted to provide an air sensor signal indicative of air in the air removal device housing;

an air removal device purge line coupled to the air removal device purge port and extending to a purge line connector adapted to be coupled to a vacuum source to apply suction to the air removal device purge port to draw air therefrom;

providing an AAR controller operating under the control of an AAR operating algorithm;

locating a portion of the air removal purge line extending through a purge valve of the AAR controller, the purge valve movable between a purge valve open position and a purge valve closed position;

coupling the air sensor with the AAR controller;

commencing the AAR controller operating algorithm that:

enters a self-test mode that performs specified self-tests of components and operating conditions of the AAR controller;

progresses to a standby mode when self-tests are completed to monitor specified components and operating conditions of the AAR controller, to power the air sensor, and to monitor the air sensor signal; and responds to a perfusionist initiated command to enter an automatic mode from the standby mode enabling automatic movement of the purge valve from the closed position to the open position when the air sensor signal is indicative of air in the air removal device housing to allow air sensed in the air removal device to be purged through the purge line by the suction of the vacuum source;

wherein the error determining step comprises determining an error state of the air sensor; and

further comprising: connecting an air sensor cable between the AAR controller and the air sensor; and wherein the error determining step determines if electrical continuity is present in the connection of the air sensor cable between the AAR controller and the air sensor.

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37. (Amended) [[The operating method of claim 31,]] A method of operating an active air removal (AAR) system to purge air from an integrated extracorporeal blood circuit providing extracorporeal oxygenation of a patient's blood during cardiopulmonary bypass surgery adapted to be performed in the presence of a perfusionist on a patient in an operating room, the operating method comprising:

providing an air removal device incorporated in the extracorporeal blood circuit, the air removal device comprising:

an air removal device housing enclosing a chamber;

an air removal device purge port through the housing to the chamber;

an air sensor supported by the air removal device housing adapted to provide an air sensor signal indicative of air in the air removal device housing;

an air removal device purge line coupled to the air removal device purge port and extending to a purge line connector adapted to be coupled to a vacuum source to apply suction to the air removal device purge port to draw air therefrom;

providing an AAR controller operating under the control of an AAR operating algorithm;

locating a portion of the air removal purge line extending through a purge valve of the AAR controller, the purge valve movable between a purge valve open position and a purge valve closed position;

coupling the air sensor with the AAR controller;

commencing the AAR controller operating algorithm that:

enters a self-test mode that performs specified self-tests of components and operating conditions of the AAR controller;

progresses to a standby mode when self-tests are completed to monitor specified components and operating conditions of the AAR controller, to power the air sensor, and to monitor the air sensor signal; and responds to a perfusionist initiated command to enter an automatic mode from the standby mode enabling automatic movement of the purge valve from the closed position to the open position when the air sensor signal is

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indicative of air in the air removal device housing to allow air sensed in the air removal device to be purged through the purge line by the suction of the vacuum source;  
determining an error state of the purging system;  
inhibiting the automatic movement of the purge valve from the closed position to the open position in the automatic mode when an error state is detected; and  
wherein the error determining step comprises determining a low vacuum condition.

38. (Original) The operating method of claim 37, wherein: the AAR controller further comprises a vacuum sensor arranged with respect to the purge line to provide a vacuum signal indicative of vacuum in the purge line; the error determining step determines a low vacuum error state if the sensed vacuum falls below a minimum vacuum.

39. (Amended) [[The operating method of claim 31,]] A method of operating an active air removal (AAR) system to purge air from an integrated extracorporeal blood circuit providing extracorporeal oxygenation of a patient's blood during cardiopulmonary bypass surgery adapted to be performed in the presence of a perfusionist on a patient in an operating room, the operating method comprising:

providing an air removal device incorporated in the extracorporeal blood circuit,  
the air removal device comprising:

an air removal device housing enclosing a chamber;

an air removal device purge port through the housing to the chamber;

an air sensor supported by the air removal device housing adapted to provide an air sensor signal indicative of air in the air removal device housing;

an air removal device purge line coupled to the air removal device purge port and extending to a purge line connector adapted to be coupled to a vacuum source to apply suction to the air removal device purge port to draw air therefrom;

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providing an AAR controller operating under the control of an AAR operating algorithm;

locating a portion of the air removal purge line extending through a purge valve of the AAR controller, the purge valve movable between a purge valve open position and a purge valve closed position;

coupling the air sensor with the AAR controller;

commencing the AAR controller operating algorithm that:

enters a self-test mode that performs specified self-tests of components and operating conditions of the AAR controller;

progresses to a standby mode when self-tests are completed to monitor specified components and operating conditions of the AAR controller, to power the air sensor, and to monitor the air sensor signal; and responds to a perfusionist initiated command to enter an automatic mode from the standby mode enabling automatic movement of the purge valve from the closed position to the open position when the air sensor signal is indicative of air in the air removal device housing to allow air sensed in the air removal device to be purged through the purge line by the suction of the vacuum source;

determining an error state of the purging system;

inhibiting the automatic movement of the purge valve from the closed position to the open position in the automatic mode when an error state is detected; and

wherein the error determining step comprises determining a purge valve error state of the purge valve.

40. (Original) The operating method of claim 39, wherein the purge valve error state determining step comprises:

commanding the purge valve to move into one of the purge valve open and closed positions;

sensing the purge valve position and providing a purge valve position signal indicative of the actual position of the purge valve; and

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determining a position error state of the purge valve or the purge valve operating means when the sensed purge valve position signal does not confirm that the purge valve is in the commanded purge valve open position or purge valve closed position.

41. (Amended) The operating method of claim [[21]] 39, wherein: the purge valve comprises a pinch valve having a valve slot receiving the portion of the purge line and a pinch rod adapted to be moved between a purge valve closed position extending into the slot to compress the purge line and a purge valve open position retracted out of the slot; and

the purge valve opening step comprises moving the pinch rod from the purge valve closed position to the purge valve open position.

42. (Original) The operating method of claim 41, further comprising: determining a pinch valve error state of the pinch valve; and inhibiting the automatic movement of the pinch valve from the closed position to the open position in the automatic mode when a pinch valve error state is detected.

43. (Original) The operating method of claim 42, wherein the pinch valve error state determining step comprises:

commanding the pinch rod to move into one of the purge valve open and closed positions;

sensing the pinch rod position and providing a pinch rod position signal indicative of the actual position of the pinch rod; and

determining a position error state of the pinch valve when the pinch rod position signal does not confirm that the pinch rod is in the commanded purge valve open or purge valve closed position.

44. (Amended) [[The operating method of claim 21, ]] A method of operating an active

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air removal (AAR) system to purge air from an integrated extracorporeal blood circuit providing extracorporeal oxygenation of a patient's blood during cardiopulmonary bypass surgery adapted to be performed in the presence of a perfusionist on a patient in an operating room, the operating method comprising:

providing an air removal device incorporated in the extracorporeal blood circuit, the air removal device comprising:

an air removal device housing enclosing a chamber;

an air removal device purge port through the housing to the chamber;

an air sensor supported by the air removal device housing adapted to provide an air sensor signal indicative of air in the air removal device housing;

an air removal device purge line coupled to the air removal device purge port and extending to a purge line connector adapted to be coupled to a vacuum source to apply suction to the air removal device purge port to draw air therefrom;

providing an AAR controller operating under the control of an AAR operating algorithm;

locating a portion of the air removal purge line extending through a purge valve of the AAR controller, the purge valve movable between a purge valve open position and a purge valve closed position;

coupling the air sensor with the AAR controller;

commencing the AAR controller operating algorithm that:

enters a self-test mode that performs specified self-tests of components and operating conditions of the AAR controller;

progresses to a standby mode when self-tests are completed to monitor specified components and operating conditions of the AAR controller, to power the air sensor, and to monitor the air sensor signal; and responds to a perfusionist initiated command to enter an automatic mode from the standby mode enabling automatic movement of the purge valve from the closed position to the open position when the air sensor signal is

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indicative of air in the air removal device housing to allow air sensed in the air removal  
device to be purged through the purge line by the suction of the vacuum source;

wherein: the AAR controller further comprises a vacuum sensor arranged with  
respect to the purge line to provide a vacuum signal indicative of vacuum in the purge  
line when the purge valve is closed; and

determining if the sensed vacuum exceeds a minimum vacuum; and

issuing an alert if the sensed vacuum does not exceed the minimum vacuum.